**REMARKS**

Claims 23-44 are presently pending.

The Office Action mailed June 26, 2006 (henceforth referred to as the "Office Action") rejected claims 23, 26, 33-34 and 36 under 35 U.S.C. § 103(a) as allegedly being upatentable as being rendered obvious by U.S. Patent No. 4,533,345 to Louw (henceforth, "Louw") in view of U.S. Patent No. 5,836,921 to Mahurkar (henceforth, "Mahurkar"). Further, claim 24 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw and Mahurkar in further view of U.S. Patent No. 4,932,947 to Cardwell (henceforth, "Cardwell"). Additionally, claims 25, 32, and 44 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw and Mahurkar in further view of U.S. Patent No. 5,007,903 to Ellard (henceforth, "Ellard"). Also, claims 27-28, 31, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw and Mahurkar in further view of U.S. Patent No. 5,494,044 to Sundberg (henceforth, "Sundberg"). Furthermore, claim 29 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw, Mahurkar, and Sundberg in further view of U.S. Patent No. 4,265,249 to Schindler et al. (henceforth, "Schindler"). Likewise, claim 30 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw, Mahurkar, and Sundberg in further view of U.S. Patent No. 5,238,003 to Baidwan et al. (henceforth, "Baidwan").

Also with respect to the methods of the present invention, claims 37-39 and 43 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw and Mahurkar in further view of U.S. Patent No. 4,744,789 to Johnson (henceforth, "Johnson"). Additionally, claims 40-42 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable as being rendered obvious by the combination of Louw, Mahurkar, and Johnson in further view of Sundberg.

Reconsideration in view of the following remarks is respectfully requested.

Claim Rejections

Each of the prior art grounds for claim rejections are addressed below according to the various references.

Ellard & Mahurkar

In the remarks of various papers previously submitted by the Applicant, it has been noted that both prior art references previously relied upon by the Examiner as primary references from the syringe field, namely Ellard and Mahurkar, failed to anticipate or render obvious the present invention for various reasons. While these two references are only now relied upon by the present Office Action as secondary prior art references, Applicant first believes it is helpful to reiterate the various ways in which the present claims distinguish over these references for the record as this will help illustrate how the new primary prior art references (namely, Louw and Johnson) likewise do not teach these features of the invention when properly read and, in fact, cannot be combined with Ellard or Mahurkar to teach the present invention.

First, both Ellard or Mahurkar teach hypodermic needle-type syringe devices. Thus, neither reference teaches a device that incorporates a flexible catheter as described in the present claims that would be suitable for purposes other than giving a hypodermic or intravenous injection. Likewise, as neither device is adapted for or intended to be used for the introduction and/or collection of fluid and particulate materials from an internal cavity, one of ordinary skill in the art would find no motivation from these references to modify them in any manner to produce an apparatus for obtaining biological samples or related methods as presently recited in the claims.

Second, neither Ellard or Mahurkar teach a device that incorporates a syringe-type actuation mechanism as present in certain embodiments present invention that causes the unique actuation recited in the various claims. In particular, claims 23 and 43 recite how the catheter is "in operative engagement" with the plunger such that axial movement of the plunger within the barrel not only evacuates/aspirates fluid from/into the barrel chamber via the catheter, but that same movement also simultaneously causes the catheter to extend/retract in length relative to the barrel. Claims 37 and 43 recites steps that include simultaneously penetrating into a cavity while

passing wash fluid, and simultaneously retracting from the cavity while aspirating a fluid sample. The prior art devices are structured and operate very differently and are not suitable for the purposes proposed by the Applicant for the present invention.

In particular, Mahurkar's device utilizes a plunger twisting mechanism (controlled by locking latch 50) that is completely independent from the axial movement of the plunger to control extension and retraction of the catheter. Thus, simultaneous fluid evacuation/aspiration and catheter extension/retraction is impossible using the taught device. Similarly, Ellard uses a cord 36 (such as a collapsible piece of plastic, similar to a sewing thread) to connect its plunger (piston element 18) to the portion of the syringe on which needle 28 is mounted (piston element 16). Ellard therefore can only extend the needle out from the barrel by the plunger physically pressing against the piston element 16 (meaning the fluid chamber formed between elements 16 and 18 is completely evacuated). Likewise, the device taught by Ellard can only have its needle retracted into the barrel by the plunger physically tugging on the cord 36 (meaning the fluid chamber formed between elements 16 and 18 is already extended to its greatest possible volume). Thus, it is physically impossible for axial movement of the plunger in Ellard to cause a catheter to extend/retract while simultaneously causing a fluid chamber to expel/aspirate fluid through that same catheter. Furthermore, it is clear that Ellard cannot teach anything relevant to one skilled in the art with respect to the recited steps of claims 37 and 43 as Ellard shows nothing that would suggest the steps of simultaneously penetrating into a cavity while passing wash fluid, or simultaneously retracting from the cavity while aspirating a fluid sample.

Therefore, both Ellard and Mahurkar are deficient prior art for at least these reasons.

Louw

Claims 23-36 and 43-44 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Louw as viewed in light of Mahurkar. Various secondary references, including Ellard, Sundberg, Schindler, and Baidwan, were also applied by the Office Action to the various dependent claims, and those references are addressed below to the extent relevant. Insofar as these rejections apply to these claims as previously presented, Applicant respectfully traverses as follows.

With regard to all of these claims, the Office Action alleges that "Louw discloses a device ... that teaches all the limitations of the claim except that Louw does not teach a device comprising a barrel and a plunger." *See* Office Action at pg. 3. The Office Action also alleges that Mahurkar teaches a device having a plunger and barrel, and having an extendable catheter attached to the plunger. *Id.* The Office Action thereafter summarily concludes that one skilled in the art would be motivated to modify Louw to include a plunger and barrel design as recited by Applicant's claims after reviewing Marhurkar. This incorrect characterization of the prior art and how one skilled in the art would be motivated by them renders the present prior art rejections applying Louw completely flawed.

First, it is noted that Louw discloses a device that is intended to be used for non-surgical procedures where perfusion of the uterus is necessary. Conventionally during such procedures, fluid is pumped into the uterus via a first catheter while that same fluid is simultaneously pumped (via a suction) out of the uterus via a second catheter. Notably, Fig. 1 of Louw shows a suction (negative pressure) applied at 13 while a supply of fluid is provided at 8 (under positive pressure). In operation, the Louw device sends fluid from a supply source under positive pressure through an inner catheter 17 where it is introduced into the uterus via holes 14. Later, (or simultaneously when it is desirous to maintain a constant fluid volume within the uterus during perfusion procedures), fluid is aspirated through catheter 16 (which is different from catheter 7) by application of a negative pressure (i.e., suction) at 13 so that the aspirated fluid is collected in reservoir 12.

Thus, Louw differs from the features of the device as recited in independent claims 23 and 37 in that its device passes fluid:

a) from a first supply chamber (supply at 8)

b) through a first catheter 17 into the cavity

where it then is subsequently (or at the same time if constant cavity fluid volume is desired)

c) aspirated through a second, different catheter 16 from the cavity

b) and deposited at a second, different location, (reservoir 12), due to the suction at 13.

The device of Louw as properly understood operates such that the suction (negative pressure) and

supply (positive pressure) of the fluid is caused by different mechanisms that can be controlled independent of each other. Further, the mechanism used by Louw for extending the catheter (namely, manifold 3) has absolutely no impact upon the passing of fluid into or out of any chamber of the Louw device. In this regard, the device of Louw is best understood as operating in a manner similar to the device of Gravlee (which device was previously distinguished by the Applicant in Responses to prior Office Actions).

Conversely, both claims 23 and 42 recite that a catheter is "in operative engagement" with a plunger and in "fluid communication" with a chamber such that axial movement of the plunger within a barrel not only evacuates/aspirates fluid from/into the chamber via the catheter, but that same movement also simultaneously causes the catheter to extend/retract in length relative to the barrel. Louw clearly does not meet these limitations of the present claims. It does not disclose, teach or suggest a device having a catheter in fluid communication with a chamber formed by a plunger and barrel. It also does not disclose a catheter in operative engagement with a plunger such that axial movement of the plunger causes the catheter to extend/retract while also causing the volume of the fluid chamber to change (and thus passing/aspirating fluid through the catheter simultaneously). While the device of Louw is clearly intended to be used for insertion into the uterus and to deliver and aspirate fluid therefrom, the fact remains that the device clearly lacks and does not suggest or motivate one skilled in the art to modify it to have the ability to extend/retract the catheter while simultaneously passing/aspirating fluid as recited in the claims.

Likewise, both independent claims 37 and 42 recite methods that include steps of penetrating into a cavity with the catheter while simultaneously passing wash fluid, and retracting the catheter from the cavity while simultaneously aspirating a fluid sample. As Louw teaches separate collection and supply catheters and chambers, and also teaches a catheter extension mechanism that operates completely independent of all of these catheters/chambers, it clearly does not teach or suggest these features recited by the claims.

As noted above, while Mahurkar and Ellard disclose syringe-type hypodermic needle devices, neither of those references disclose or suggest devices that have the ability to extend/retract a catheter while simultaneously passing/aspirating fluid as recited in these particular steps of collection methods as recited in the claims. As such, Applicant respectfully

submits that Louw, both alone and in combination with Mahurkar and Ellard, fails to teach or suggest various features of the claimed invention as outlined above.

Thus, all claims currently pending are presently allowable over the combined teachings of Louw, Ellard, and Marhurkar.

Johnson

Claims 37-44 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combined teachings of Louw and Mahurkar, in further view of Johnson. Insofar as these rejections apply to these claims as previously presented, Applicant respectfully traverses as follows.

With regard to all of these claims, the Office Action first admits that neither Louw or Mahurkar "does not teach the steps of simultaneously moving the catheter and washing and/or collecting fluid from the internal cavity." However, it nonetheless rejects the method claims as it improperly alleges that "Johnson discloses a method of injecting fluid into an internal body cavity comprising the step of penetrating of the internal body cavity and injecting the fluid during said penetrating (see figs. 11A-B)." *See* Office Action at pg. 9. Again, the Office Action grossly overstates what the asserted prior art teaches, rendering this grounds for rejection wholly improper.

Specifically, it should be noted that Johnson teaches nothing with respect to the injection and/or collection of fluid from "an internal cavity." Upon proper reading, it is clear that Johnson relates to cosmetic surgical procedures for fat removal and redistribution (see, e.g., Johnson at FIG. 1). Johnson discloses a first hypodermic needle 34 attached to a high powered suction source 18 for sucking fat cells out from under the skin layer of a patient. This extracted fat is then redistributed to other areas of the patient with a second hypodermic needle 40. Apparently, the Office Action has focused on the fact that Johnson teaches that this second hypodermic needle may be placed within an injection gun 50 to assist in distributing the injected fat uniformly under the skin at the target site. However, this feature of Johnson does not teach or suggest any steps for fluid collection from an internal cavity as is recited in all of claims 37-44.

In particular, it first is pointed out that Johnson relates to the collection and injection of

fat below the skin. It does not in any way relate to or otherwise have application to procedures for collecting biological samples from an internal cavity, such as a uterus. In this regard, Johnson is completely void of any disclosure or teaching of passing a fluid into or collecting fluid from an internal cavity of a patient or penetrating a catheter into or retracting that catheter from such a cavity.

Second, Johnson does not teach "injecting fluid into an internal body cavity" by "penetrating [into] the internal body cavity and injecting the fluid during said penetrating" as alleged. Referring to the portions of Johnson's specification describing FIGs. 11A and 11B, it is apparent that Johnson is attempting to devise a surgical device for simplifying the manual technique employed by cosmetic surgeons whereby one uses a standard hypodermic needle syringe to inject fat under the skin while simultaneously withdrawing the needle from the skin in order to spread the injected fat through different locations/layers of the skin. *See* Johnson at col. 2 and 5. This teaching is completely inapplicable to the present invention as it relates to hypodermic injection, it describes only an injection step, and moreover, this injection step operates opposite to the fluid passing step recited in Applicant's claims 37 and 43.

As shown in FIG. 11A and FIG. 11B, the process automated by the gun device of Johnson is where a hypodermic needle 42 (already inserted under the skin at the injection site) is slowly withdrawn from the skin while the plunger 44 is slowly depressed. Thus, the gun device of Johnson (which notably lacks various features of Applicant's devices as recited in independent 43) automates a process whereby injection (e.g., fluid passing) occurs while the needle is retracted from the skin. This is, of course, completely the opposite of passing fluid while entering into the skin (let alone penetrating into a cavity while passing fluid, as is claimed).

Since Johnson is completely silent with respect to passing fluid into and collecting sample fluid from an internal cavity, and since the portions of that reference relied upon by the Office Action teach exactly the opposite of Applicant's claimed steps, it is clear that a prima facie case for obviousness has not been met for all claims wherein Johnson is improperly applied. As such, immediate removal of all grounds for rejection relying upon Johnson is warranted.

Baidwan, Sundberg, and Schindler

All claims are allowable over the prior art of record for the above described reasons, and none of the secondary references, namely, Baidwan, Sundberg, or Schindler, alone or in combination, remedy the deficiencies outlined above. Thus, immediate allowance of all claims is warranted given the allowability of the independent claims.

Request for Formal In-person Examiner Interview

Applicant hereby requests a formal, in-person interview with the Examiner and the Supervisory Examiner for Art Unit 3736 once the Examiner has had sufficient time to consider the remarks set forth herein. In particular, Applicant believes that there are many clear and significant differences between the plethora of prior art references from different fields and the claims as presently recited.

In this regard, Applicant believes that an in-person demonstration of a working device according to the present invention may help illuminate the features of the claimed invention to the Examiner and the Supervisory Examiner and avoid the need for further time consuming and costly Office Actions and a subsequent appeal to the Board of Patent Appeals and Interferences. As such, Applicant will contact the Examiner via telephone within a month after filing this paper in order to reiterate this request and schedule an in-person interview to conduct such a demonstration.

## Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the claims as amended for examination on the merits. A timely allowance of the pending claims is requested.

Applicant has not herein increased the number of claims beyond the amount for which "additional claims fees" have been previously paid and has not incurred any extensions of time. If, however, a fee necessary for the consideration of this paper has not been specifically submitted through error, please charge any additional fees (or credit any overpayments) to Deposit Account No. 50-1349.

The Examiner is specifically invited to contact Applicants' undersigned attorneys by telephone to discuss the present claims if the Examiner would like to discuss additional claim language that would allow the present application to go toward immediate allowance, or to schedule an appropriate time for a prototype demonstration as requested above.

Respectfully submitted,

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